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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/193,221 11/16/98 MALINOW

R A-67162/BIR

EXAMINER

HM12/0201

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TURNER, S	
ART UNIT	PAPER NUMBER

1644

11

DATE MAILED:

02/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/193,221

Applicant(s)

Mallnow

Examiner

Sharon L. Turner, Ph.D.

Group Art Unit

1644

☒ Responsive to communication(s) filed on 11-22-99

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-12 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-12 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1644

Response to Amendment

1. The Examiner of U.S. Patent application SN 09/193,221 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1644.
2. The amendment filed 11-22-99 has been entered into the record and has been fully considered. Claims 1-12 are pending.
3. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

Rejections Maintained

Claim Rejections - 35 USC § 112 first paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 stand rejected under 35 U.S.C. 112, first paragraph, for the reasons of record in Paper No. 11, mailed 8-18-99, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Applicants argue that the phrase which defines the nature of the cells, namely "having enhanced synaptic potentiation upon stimulation as compared to wild-type hippocampal cells" is eliminated from consideration. Regardless of the mutation the cells must fulfill the requirement of having enhanced potentiation and so long as it has this effect it is within the scope of the claims. Further, applicant argues that the Parent reference fulfills this requirement of enhanced potentiation and supports the evidence presented in instant application, whether or not there is a difference in the observed fEPSP.

These arguments have been fully considered but are not persuasive as the scope of the claims are not commensurate in scope with enablement. As set forth in Paper No. 11, mailed 8-18-99, Parent et al teach that no difference was observed between wild-type and mutant hippocampal cells in response to tetanic stimulation which thus represents an example in which applicants method seemingly is contradictory given the Parent cells are also mutant hippocampal cells which do not exhibit enhanced synaptic potentiation. Further, although Parent provides for methods of enhancing long term potentiation in such cells it is clear that this activity is dependent upon many factors which affect synaptic activity including the type of "mutation" the history of synaptic activity, the type of stimulation provided and the measured result, for example fEPSP which is relevant to the determination of synaptic long term potentiation, i.e. a relationship between a presynaptic and postsynaptic nerve. Thus, given the quantity of experimentation necessary for every mutant cell and synaptic history, the unpredictability of the art, the lack of

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sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Claim Rejections - 35 USC § 112 second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6 and 8-9 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "statistically significant change" in said claims is still a relative term which renders the claims indefinite because there is no direction as to what level of statistical significance one must achieve. The specification does not provide a standard for ascertaining the requisite degree of change required to exactly constitute a "statistically significant change", and one skilled in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 10 stands rejected under 35 U.S.C. 102(b) as being anticipated by Borchelt et al (October 1997 reference; see PTO-892). Claim 10 is drawn to slices of mouse hippocampal cells having a mutation in a presenilin gene combined with a candidate drug.

Applicants argue that the examiner has misinterpreted the terms in the claim and that by not stretch of the imagination can one consider an antibody for a neural protein to be a candidate drug.

This argument has been fully considered but is not persuasive. There is no reason why an antibody can not be considered a drug since antibodies specifically target and bind to proteins and may be used to block or alter activity. Thus, Borchelt anticipates claim 10.

Status of Claims

6. No claims are allowed.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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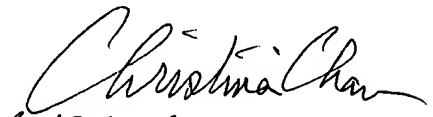
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

5. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973.

Sharon L. Turner, Ph.D.
January 27, 2000


CHRISTINA CHAN
SUPERVISOR, PATENT EXAMINER
GROUP 1800 (GEO)